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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,678	12/06/2001	John E. Hutchins	BSX-214.1CIP	3101

7590 01/23/2004

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EXAMINER
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WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/003,678

Applicant(s)

HUTCHINS ET AL. JH

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 12-17, 21, 23-27, 30-33 and 36-41 is/are rejected.
- 7) ☒ Claim(s) 5-8, 10, 11, 18-20, 22, 28, 29, 34 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 8-10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 33, "the channel" lacks antecedent basis. With respect to claim 36, "said cutting wire" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 9, 12-17, 21, 23-27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver et al. (5,599,300). Weaver et al. disclose, in figures 4 and 34-36 and in col. 19, lines 11-66, an apparatus, a catheter handle (202), or a catheter (12), and a method of cutting tissue in a body passage, where the catheter has proximal and distal ends and first or guidewire and second lumens (32, 34) and an electrosurgical cutting wire (206), where the handle engages and rotates the proximal end of the cutting wire (about its axis during assembly) and has a clamping member

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(224) for the cutting wire, a rotatable coupling (14, see also col. 19, lines 16-20) attaching the handle to the catheter, a locking mechanism (209), rotation lock (17, a threaded luer lock hub according to col. 19, lines 52-60), a rotation indicator or a visual indicator of handle rotation (distal surface portion of 17), a second locking mechanism (221), and an endoscope (36).

5. Claims 31, 32, and 36-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita et al. (5,342,292). With respect to claims 31, 32, and 37, Nita et al. disclose, in figures 2-12a, a catheter (12) and a method for its use in positioning a cutting device, where the catheter and method include a guidewire lumen (14), a cutting device (20, 22), first and second openings (13) through the catheter wall, and a locking mechanism (140a, b, or c) for locking an orientation of the distal portion of the cutting device, and a second locking mechanism (210, 212). With respect to claims 38-41, Nita et al., in figures 5, 6, 8a, and 12a, a catheter with a thinned exterior wall adjacent the guidewire lumen (14b), a first opening into the guidewire lumen (13), a cutting device (22) with cutting wire (20), a handle (146) locking mechanism (140a or b), a rotation indicator (concavity 142c, which prevents rotation of the handle when it is positioned in the concavity), and a second locking mechanism (210, 212).

***Allowable Subject Matter***

6. Claims 5-8, 10, 11, 18-20, 22, 28, 29, 34, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an apparatus having, inter alia, a catheter, a cutting wire, a catheter handle for the cutting wire, a rotatable coupling attaching the handle to the catheter, a locking mechanism for locking an orientation of the distal portion of the cutting wire, and a handle rotation indicator; and a method for use of the apparatus, where rotation of the handle relative to the proximal end of the catheter is indicated audibly or with an index marking and a corresponding scale marking, where the locking mechanism includes an insert for resisting movement between moving parts of the apparatus or of a guidewire, and where the locking mechanism or a second locking mechanism includes evenly-spaced detents.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

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**Conclusion**

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nita et al. (5,957,882) teach a catheter with a guidewire lumen.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9306.



Julian W. Woo  
Primary Examiner

January 21, 2004